

TRANSDERM IQ- transderm iq patch
TRANSDERM IQ- transderm iq ointment
DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Transderm IQ

Active ingredients:

Lidocaine HCL 4%

Menthol 4%

Purpose:

Topical Anesthetic

Uses:

For the temporary relief of pain

Warnings:

For external use

Do not use:

More than 1 patch on your body at a time or on cut, irritated or swollen skin.

On puncture wounds

For more than 1 week without consulting a doctor

When using this product:

Use only as directed. Read and follow all directions and warnings on this label.

Rare cases of serious burns have been reported with products of this type.

Do not apply to wounds or damaged, broken or irritated skin.

Do not allow contact with the eyes and mucous membranes.

Do not bandage tightly or apply local heat (such as heating pads) to the area of use.

Do not use at the same time as other topical analgesics.

Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if:

Condition worsens

Redness is present

Irritation develops

Symptoms persist for more than 7 days or clear up and occur again within a few days.

You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children over 12 years:

Clean and dry the affected area.

Open pouch and remove one patch.

Remove the protective film from the patch and apply patch to the affected area.

Reseal pouch containing unused patches after each use.

Use 1 patch for up to 12 hours.

Children 12 years or younger:

Ask a doctor

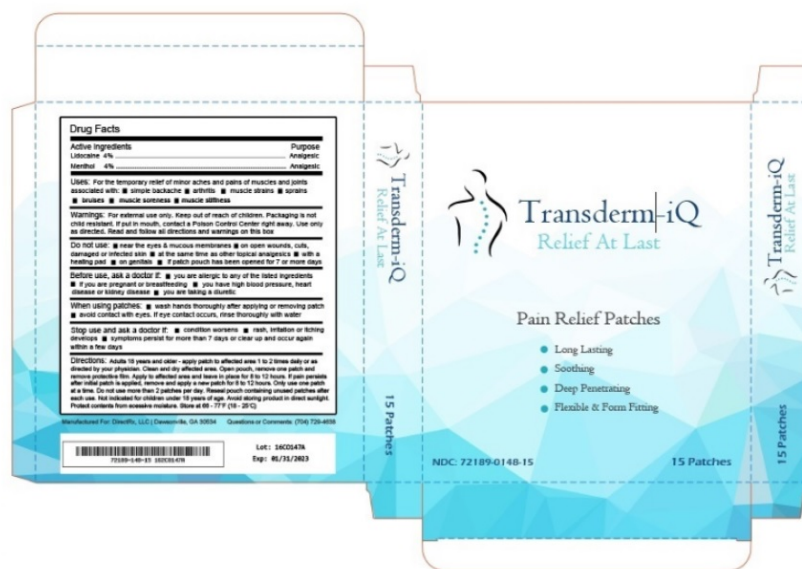
Other Information:

Avoid storing product in direct sunlight

Protect product from excessive moisture

Other Ingredients:

Acrylic Adhesive



DRUG FACTS LABEL

Drug Facts

| Active Ingredients | Purpose |
|--------------------|------------|
| Lidocaine 4% | Anesthetic |
| Menthol 4% | Anesthetic |

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ muscle strains ■ sprains ■ bruises ■ muscle soreness ■ muscle stiffness

Warnings: For external use only. Keep out of reach of children. Packaging is not child resistant. If put in mouth, contact a Poison Control Center right away. Use only as directed. Read and follow all directions and warnings on this box.

Do not use: ■ near the eyes & mucous membranes ■ on open wounds, cuts, damaged or infected skin ■ at the same time as other topical anesthetics ■ with a heating pad ■ on genitals ■ if patch pouch has been opened for 7 or more days

Before use, ask a doctor if: ■ you are allergic to any of the listed ingredients ■ if you are pregnant or breastfeeding ■ you have high blood pressure, heart disease or kidney disease ■ you are taking a diuretic

When using patches: ■ wash hands thoroughly after applying or removing patch ■ avoid contact with eyes. If eye contact occurs, rinse thoroughly with water

Stop use and ask a doctor if: ■ condition worsens ■ rash, irritation or itching develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days

Directions: Adults 18 years and older - apply patch to affected area 1 to 2 times daily or as directed by your physician. Clean and dry affected area. Open pouch, remove one patch and remove protective film. Apply to affected area and leave in place for 8 to 12 hours. If pain persists after initial patch is applied, remove and apply a new patch for 8 to 12 hours. Only use one patch at a time. Do not use more than 2 patches per day. Reseal pouch containing unused patches after each use. Not indicated for children under 18 years of age. Avoid storing product in direct sunlight. Protect contents from excessive moisture. Store at 66 - 77°F (18 - 25°C).

Drug Facts

| Active Ingredients | | Purpose |
|--------------------|----|-------------------|
| Lidocaine | 4% | Topical Analgesic |
| Menthol | 1% | Topical Analgesic |

Uses: temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache ■ arthritis ■ muscle strains
- sprains ■ bruises

Warnings: For external use only

- use only as directed. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- do not use at the same time as other topical analgesics
- do not use on open wounds, cuts, damaged or infected skin
- do not use with bandage or heating pad

Stop use and ask a doctor if:

- condition worsens
- symptoms persist more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding or if you have sensitive skin, ask a healthcare professional before use.

- if swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults 18 years & children 12 years and older:

- apply product directly to affected area
- product may be used as necessary, but should not be used more than four times per day
- wash hands immediately after application

Questions/Comments: (305) 477-8111

Other Ingredients: Allantoin, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Ammonium Acryloyldimethyltaurate /VP Copolymer, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Capsaicin, Cetyl Alcohol, Dimethicone, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Ilex Paraguariensis (Yerba Mate) Extract, Inulin Lauryl Carbamate, Magnesium Sulfate, Methyl Salicylate, PEG-100 Stearate, Phenoxyethanol, Stearic Acid, Tetrasodium EDTA, Triethanolamine.

Manufactured by Pure Source, LLC
9750 NW 17th Street, Miami, FL 33172

Manufactured Exclusively for DirectRx, LLC
94 Worldwide Dr, Dawsonville, GA 30534



72189016604DirectRx

72189-0166-04



Transderm-iQ

Relief At Last.

Topical Pain Relief Ointment

New & Improved Formula
New Hands Free Applicator

Long Lasting and Soothing
Deep Penetrating Action

Net WT 4 oz. (121 g)

TRANSDERM IQ

transderm iq patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72189-148(NDC:70512-013) |
| Route of Administration | TRANSDERMAL | | |

| Active Ingredient/Active Moiety | | |
|---|---------------------------|--------------|
| Ingredient Name | Basis of Strength | Strength |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 40 mg in 1 g |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 40 mg in 1 g |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ACRYLIC ACID (UNII: J94PBK7X8S) | |

| Product Characteristics | | | |
|-------------------------|-----------|--------------|--|
| Color | | Score | |
| Shape | RECTANGLE | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72189-148-15 | 15 in 1 BOX | 04/07/2021 | |
| 1 | | 1 g in 1 PATCH; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348 | 04/07/2021 | |

TRANSDERM IQ

transderm iq ointment

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72189-166 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---------------------------------|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| | | |

| | | | | |
|--|--|--|---------------------------|--------------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | | | LIDOCAINE | 40 mg in 1 g |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | | | MENTHOL, UNSPECIFIED FORM | 40 mg in 1 g |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| ACRYLIC ACID (UNII: J94PBK7X8S) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72189-166-04 | 1 g in 1 BOTTLE; Type 0: Not a Combination Product | 06/04/2021 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348 | | 06/04/2021 | |

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------|---------|-----------|---|
| DIRECT RX | | 079254320 | relabel(72189-148) , manufacture(72189-166) |

Revised: 6/2021

DIRECT RX